Dupilumab Improves Patient-Reported Outcomes as Early as 1 Month among Adults with Prurigo Nodularis in Clinical Practice: Initial Results from the RELIEVE-PN Study

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Dupilumab

BACKGROUND

- Dupilumab, a human monoclonal antibody, has been approved by the United States Food and Drug Administration (FDA) and the European Medicines Agency (EMA) for the treatment of adults with prurigo nodularis (PN).[1]
- In the pivotal phase 3 clinical trials LIBERTY PN-PRIME (NCT04183335) and PRIME2 (NCT04202679), dupilumab demonstrated a significant improvement in multiple measures of symptoms (including itch and skin pain) and health-related quality of life (HRQoL).[2] However, the real-world effectiveness of dupilumab has not yet been well established.
- The RELIEVE-PN (EaRly REal-WorLd PatIent EValuation for DupixEnt in Prurigo Nodularis) is a prospective real-world patient survey study that was initiated to demonstrate the real-world effectiveness of dupilumab for treatment of PN.

OBJECTIVE

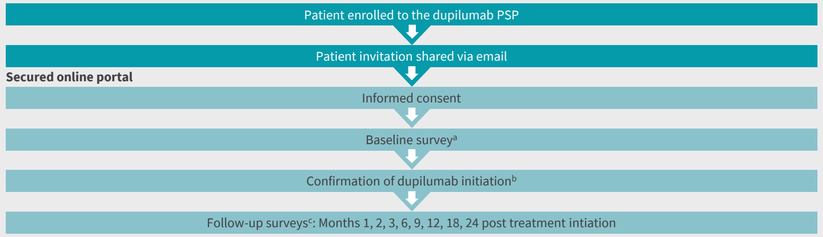
- **To evaluate the initial (one month) impact of dupilumab therapy on symptoms and treatment satisfaction among patients with prurigo nodularis in the US from the RELIEVE-PN study.**

METHODS

Study design and patient population

- RELIEVE-PN is an ongoing pre-post, observational, longitudinal patient survey study assessing the real-world effectiveness of dupilumab in the treatment of patients (aged ≥18 years) with PN (**Figure 1**).

Figure 1. RELIEVE-PN study design

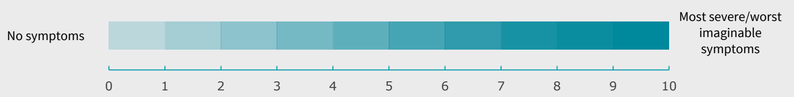


[a]The baseline survey collected data on socio-demographic characteristics, disease characteristics, medical history, PN sign/symptoms, prior treatment history and experiences, psychological wellbeing, HRQoL, employmet status, treatment satisfaction, and patient global assessments. [b]Patients were sent weekly emails, asking whether they have initiated dupilumab for 8 weeks. If a patient has not initiated dupilumab 8 weeks after the baseline survey, the patients are dis-enrolled from the study without further follow-up. [c]Follow-up survey collected data on PN sign/symptoms, HRQoL, dupilumab treatment status, treatment satisfaction and patient global assessment.
Patients who have been treated with dupilumab prior to enrollment and those who were part of a clinical trial over the past 6 months were excluded. HRQoL, health-related quality of life; PN, prurigo nodularis; PSP, patient support program.

Study outcomes

- The study utilized patient-reported outcome measures for assessing PN symptoms and treatment satisfaction pre (baseline survey) and 1-month post dupilumab initiation.
  - PN symptoms were assessed separately using the worst itch numeric rating scale (WI-NRS), average itch NRS, skin pain NRS, and skin burning or stingling/tingling NRS using a 7-day recall (**Figure 2**).
  - Treatment satisfaction with current therapy was evaluated using a 7-point Likert scale from "extremely satisfied" to "extremely dissatisfied".

Figure 2. Numeric rating scale for symptoms



Statistical analysis

- Descriptive analyses were conducted to summarize the study outcomes.
  - Continuous variables were summarized with means (SD); categorical variables were summarized with frequency count and percentage.
  - Comparison between pre and 1-month post dupilumab initiation for the outcomes were conducted using t-tests for continuous variables, and Chi-square/Fisher's exact tests for categorical variables.

RESULTS

- Of 84 patients completing the baseline survey and initiating dupilumab, 62 (73.8%, mean [SD] age: 56.38, 77.42% females) patients completed the Month 1 post-dupilumab initiation survey (**Table 1**).

Table 1. Demographic and medical history at baseline

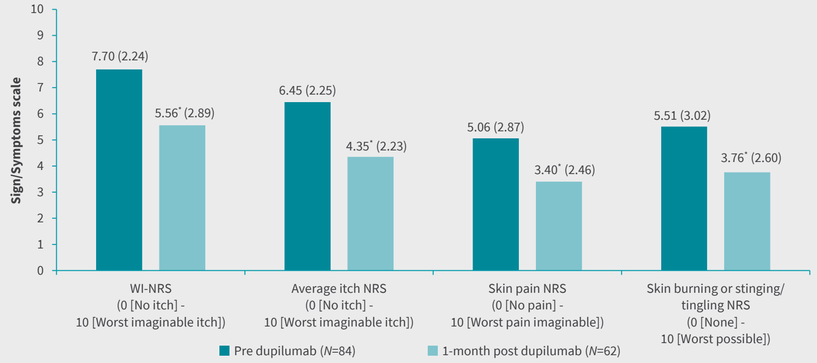
	Enrollment (*N*=84)	Patients who completed survey at month 1 (*N*=62)
Age[a], years, mean ± SD	57.50 ± 14.62	56.38 ± 15.16
Female, *n* (%)	67 (79.76)	48 (77.42)
Race, *n* (%)		
White or Caucasian	70 (83.33)	52 (83.87)
Black or African American	8 (9.52)	8 (12.90)
Asian or Pacific Islander	1 (1.19)	1 (1.61)
Native American/American Indian or Alaska Native	2 (2.38)	1 (1.61)
Multiple races or other	2 (2.38)	0 (0)
Prefer not to answer	1 (1.19)	0 (0)
Ethnicity, *n* (%)		
Hispanic or Latino	5 (5.95)	2 (3.23)
Not Hispanic or Latino	77 (91.67)	59 (95.16)
Prefer not to answer	2 (2.38)	1 (1.61)
Time since diagnosis[a, b], years, mean ± SD	0.85 ± 2.58	0.84 ± 2.87
Type 2 inflammatory comorbidities[a, c], *n* (%)	37 (44.05)	25 (40.32)
Topical therapies in the last 4 weeks[d], *n* (%)		
Any topical therapies	75 (89.29)	45 (72.58)
Steroid creams or ointments including OTC treatments	51 (60.71)	32 (51.61)
TCI creams or ointments including OTC treatments	21 (25.00)	8 (12.90)
Other topical agents (e.g., emollients, moisturizers, thick creams)	62 (73.81)	27 (43.55)
Oral therapies in the last 4 weeks[d], *n* (%)		
Any oral therapies	73 (86.90)	41 (66.13)
Oral pain medication	60 (71.43)	27 (43.55)
Antihistamines	48 (57.14)	23 (37.10)
Oral antianxiety pills	40 (47.62)	18 (29.03)
Oral anti-depressants pills	36 (42.86)	21 (33.87)
Sleep medication	14 (16.67)	7 (11.29)
Steroid pills	11 (13.10)	4 (6.45)
Injectable therapies in the last 4 weeks[d], *n* (%)		
Any Injectables	7 (8.33)	3 (4.84)
Steroid injections directly into nodules	7 (8.33)	2 (3.23)
Injectable biologics	0	1 (1.61)

[a]Measured at baseline; [b]Calculated for patients who remembered when they were first told by their doctor they had PN; [c]A patient is considered to have Type 2 inflammation if they have/had asthma, atopic dermatitis, chronic rhinosinusitis with nasal polyposis, eosinophilic esophagitis, or food allergies. [d]Values may not add up to 100% as patients may be included in more than one category.
OTC, over the counter; PN, prurigo nodularis; TCI, topical calcineurin inhibitors; SD, standard deviation.

Effectiveness of dupilumab

- At baseline, mean (SD) WI-NRS, average itch NRS, skin pain NRS, and skin burning or stingling/tingling NRS were 7.70 (2.24), 6.45 (2.25), 5.06 (2.87), and 5.51 (3.02), respectively.
- By month 1, mean (SD) WI-NRS, average itch NRS, skin pain NRS, and skin burning or stingling/tingling NRS improved to 5.56 (2.89), 4.35 (2.23), 3.40 (2.46), and 3.76 (2.60), respectively (p<0.001 for all) (**Figure 3**).

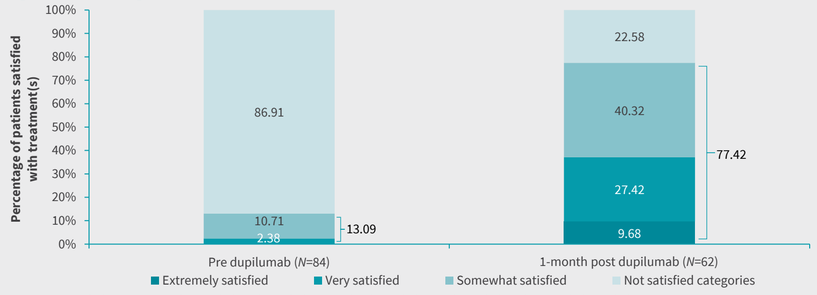
Figure 3. Improvement in sign/symptoms among patients with PN at month 1



*p<0.001; Data was represented as mean (SD).
PN, prurigo nodularis; SD, standard deviation; WI-NRS, worst-itch numeric rating scale.

- Additionally, significantly more patients reported they were satisfied with current PN treatment(s) at month 1 after dupilumab treatment initiation vs prior to starting dupilumab (77.42% vs 13.09%; p<0.001) (**Figure 4**).

Figure 4. Percentage of patients satisfied with treatment(s)



p<0.001. Not satisfied categories: 'Neither satisfied nor dissatisfied', 'Somewhat dissatisfied', 'Very dissatisfied', and 'Extremely dissatisfied'.

CONCLUSION

- **Early results from the RELIEVE-PN study demonstrate improvement in symptoms and patient satisfaction with therapy as early as 1-month from treatment initiation of dupilumab. The preliminary findings of the real-world RELIEVE-PN study are consistent with the results of dupilumab phase 3 clinical trials in PN. Future data from this study will inform the long-term real-world outcomes in this population.**

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FUNDING
The study was sponsored by Sanofi and Regeneron Pharmaceuticals Inc.

ACKNOWLEDGMENTS
Research was funded by Sanofi and Regeneron Pharmaceuticals Inc. Medical writing/editorial assistance was provided by Purushottam Shiranal and Dr. Kaushik Subramanian from Sanofi, according to the Good Publication Practice guidelines.

CONFLICTS OF INTEREST
RBT and **JZ** – Regeneron Pharmaceuticals Inc. – employees, may hold stocks and/or stock options in the company; **DB** and **SA** – Sanofi – employees, may hold stocks and/or stock options in the company; **BM, MY, JL** and **AH** – Analysis Group – employees, may hold stocks and/or stock options in the company;
SK – AbbVie, Arcutis Biotherapeutics, Asian Pharmaceuticals, Celldex Therapeutics, Galderma, Genzada Pharmaceuticals, Incyte, Johnson & Johnson, Novartis, Pfizer, Regeneron Pharmaceuticals Inc., Sanofi – advisory board member/consultant; Galderma, Incyte, Pfizer, Sanofi – investigator.
SE – Sanofi, Regeneron Pharmaceuticals, Galderma, Celldex, Pfizer, Incyte, Eli Lilly, New Frontier Bio – consultant, advisory board, lectures.

Poster presented at the Fall Clinical Dermatology Conference (FCD 2024), October 24 – 27, Wynn Las Vegas, NV, USA.